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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,005	11/02/2001	Masatoshi Noda	010969	5152

23850 7590 12/03/2002

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 12/03/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/926,005

Applicant(s)

NODA ET AL.

Examiner

Ganapathy Krishnan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8 and 10-21 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment (Paper # 10/B) filed September 16, 2002, has been received, entered into record and carefully considered. The following information provided in the amendment affects the instant application:

1. Claim 9 has been cancelled without prejudice or disclaimer.
2. Claims 1, 4-6 and 10-11 have been amended.
3. New Claims 12-21 have been added.
4. Remarks have been presented, drawn to:
 - a) 102(b) rejections
 - b) 112 first paragraph rejections regarding enablement for prevention of enterotoxin type bacterial infection.
5. Two additional references: a) Tsai, S.C. et al "Enhancement of cholera ADP-ribosyltransferase activities by guanylyl nucleotides and a 19kDa membrane protein", Proc. Natl. Acad. Sci. August 1987, vol. 84, pp 5139-5142. (b) Yanagida, A. et al « Inhibitory Mechanism of Apple Procyanidins on ADP-Ribosyltransferase Activity of Cholera Toxin », Polyphenols Communication, 2002. A PTO-1449 form listing these two references was not provided.
6. Claims 1-8 and 10-21 are pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 6-8 and 10-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Rozhon et al (WO 98/16111).

Claims 1-21 are drawn to proanthocyanidins purified to a tetramer or higher fraction as an effective ingredient; a composition for treating/preventing diphtheria, pertussis, opportunistic infections, enterotoxin type bacterial infection, cholera or botulinus or traveler's diarrhea.

Rozhon et al drawn to enteric formulations of proanthocyanidin polymers, teach pharmaceutical compositions containing proanthocyanidins used for the treatment of diarrhea (see page 1 and 12). The proanthocyanidin composition is comprised of polymers preferably 2 to 15 flavonoid units and most preferably 7 flavonoid units (see page 15, lines 23-29). They also disclose the use of the pharmaceutical compositions and method for treating diarrhea caused by enteric bacteria and traveler's diarrhea (see page 26, lines 1-5, page 27, lines 8-15 and pages 53-58, claims 1-47).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of enterotoxin type bacterial infections, does not reasonably provide enablement for the prevention of the said infection. The specification does

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not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claim.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

- (A) The breadth of the claims
- (B) The state of the prior art
- (C) The level of one of ordinary skill
- (D) The level of predictability in the art
- (E) The amount of direction provided by the inventor
- (F) The existence of working examples
- (G) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

Claim 18 is drawn to a method for prevention of enterotoxin type bacterial infection comprising administering a composition containing proanthocyanidin as an ingredient. The scope of the claim is seen to include the administration of the said composition to a healthy subject, and subsequent exposure to conditions that would cause the said infection, wherein the said composition prevents the said exposure from manifesting itself in said subject so exposed.

The state of the prior art

The examiner notes that the art cited by the applicants mention methods of treatment of enterotoxin type infections. However, there is no disclosure of potential enterotoxin type infection preventive activity of compounds seen in the prior art. The prior art appears to be silent with regard to preventive procedures recognized by skilled artisans in the field.

The level of one of ordinary skill

The skilled artisan in this field is that of an MD for chemotherapeutic administration and/or a Ph.D. skilled in the development of chemotherapeutics.

The level of predictability in the art

The examiner acknowledges the probability and predictability that administration of the said compositions would have a reasonable expectation of success for preventing the said infection. There is not seen sufficient data to substantiate the assertion that the said infection may be prevented by the use of the compositions instantly claimed.

The amount of direction provided by the inventor

The instant specification is not seen to provide enough guidance that would allow a skilled artisan to extrapolate from the disclosure and the examples provided to enable the use of the active agents to prevent enterotoxin type bacterial infections. The specification also fails to direct the skilled artisan in correlative prior art procedures which might provide the basis for an advance in treating such infections which induces prevention of the said disease.

The existence of working examples

The working examples set forth in the instant specification are drawn to data involving ligated rat gut loop. The skilled artisan in this field would not extrapolate the preventive efficacy of the composition claimed or the use of the same in preventive methods from just this example provided. The disclosure does not show the prevention of the said infection. However, it is seen to show the effect of the active agents in blocking the progression of the said infection.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure

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Indeed, in view of the information set forth, the instant disclosure is not seen to be sufficient to enable the prevention of enterotoxin type bacterial infection with the composition set forth in the claims. A skilled artisan would not extrapolate the preventive efficacy from the results disclosed for the example using the rat gut alone, set forth in the instant specifications.

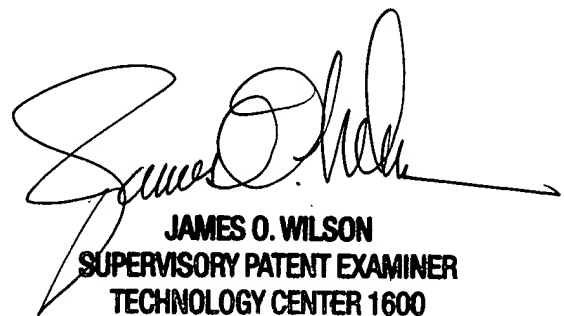
Claim 5 is objected to since it depends on a base claim that has been rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 703-305-4837. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

GK
December 2, 2002



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600